DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2605n

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WARNING LETTER

May 7, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Abraham A. Chaplan, M.D., Ph.D.
En Garde Health Products, Inc.
7702 Balboa Blvd., Bldg. #10
Van Nuys, California 91406

W/L 28-9

Dear Dr. Chaplan:

This letter is in reference to your firm's marketing and distribution of the various products listed below. Labeling for the products, which includes the "Product Information Book," contains therapeutic claims that cause the products to be "drugs" (section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)) and "new drugs" (section 201(p) of the Act). Examples of the claims for the products include the following:

Your products **CHELO$_2$ GARDE** and **CHELO$_2$ GARDE PLUS**: are offered with claims such as "powerful oral chelating effects . . . Cleans out accumulated build up on blood vessel walls," "heart attacks, strokes," "keep the arteries clear without the need for initial or repeated surgery," "removal of existing plaque and reduced the formation of new plaque," and "continuously purge the arterial system of unwanted accumulations... used preventatively as well as after by-pass operation or angioplasty, to prevent recurrence." [Page 23 of the "Product Information Book" includes a diagram showing "obstructions."]

Your product **FM**: is offered with claims for Fibromyalgia.

Your product **GINKGO BILOBA**: is offered with claims for "hypertension, varicose veins, and some circulatory diseases - Ideal for diabetics," " anti-agglutination agent (similar to aspirin)," ADHD, "prevent stroke," "reduces senile deterioration," and "platelet anti-agglutinating (anti-clumping) substance which performs a similar role to that of aspirin".

Your product **ELIMINMETAL/OUT**: is offered with claims such as "detoxify aluminum from brain and body tissues," "remove any heavier metals (e.g., lead, cadmium, mercury)," and "Attention Deficit Hyperactivity Disorders (ADHD)."

Your product **DLPA[IN]/OUT**: is offered with claims such as "effective and safe pain killer," "chronic pain," "premenstrual syndrome (PMS), reduces the swelling and inflammation of arthritis," "safe antidepressant," "as effective as commonly prescribed antidepressant drugs," "increases the effectiveness of aspirin," "pain of dysmenorrhea," and "last longer than aspirin or narcotics."

Your product **COLLOIDAL GOLD**: is offered with claims for the treatment/alleviation of conditions such as "inflammation, arthritis," "depression, anxiety, sorrow and S.A.D. (Seasonal Attitude Disorder)," "obesity and alcoholism," and "healing of skin ulcers; and for burns."

Your product **COLO ZONE PLUS**: is offered with claims to "flush out toxins, parasites and bacteria," and for "inhibiting growth of unwanted anaerobic life forms."

Your products **OXY MSM**: and **SUPER OXY DMAE-PABA**: are offered with anti-pain claims.

Your **ROYAL ARTERIAL FLUSH(kit)** and **IMPROVED ROYAL ARTERIAL FLUSH(kit)**: are offered with claims such as "Cleans out accumulated buildup on blood vessel walls," "A selective vasodilator providing the anti-agglutinating action of aspirin," "Affects all 40,000 miles of blood vessels not just the inches that by-pass operations and angioplasty address. A program to consider before surgical by-pass becomes the only choice, and for people who have had one, or angioplasty, to avoid recurrence" as well as "Repair blood vessel walls, Help blood pressure programs."

Your **ADHD NUTRITIONAL KIT**: is offered with claims for Attention Deficit Hyperactivity Disorders, to "detoxify aluminum from brain and body tissues," and "remove heavier metals (e.g., lead, cadmium, mercury)."

Your **TOTAL BODY and COLON CLEANSE KIT**: is labeled "Kills parasites and worms", "prevent any crises in healing", "cleansing of anaerobic bacteria, parasites and fungi, reduces the tendency toward hemorrhoids, "irritable bowel" and other digestive problems," and "COMBATS HEARTBURN, BLOATING, IRRITABLE BOWEL, FUNGUS, COLITIS, PARASITES, CONSTIPATION, AND MALABSORBTION."

Your product **NICOTINE/OUT: is labeled** "Don't Smoke, SPRAY!," "SUBLINGUAL NICOTINE DETOXIFIER AND QUITTER'S AID," and "Take just before entering a situation where you habitually smoke, when possible; or to lessen the desire to smoke (when present)." NICOTINE/OUT is considered a smoking deterrent under 21 CFR 310.544 (Drug products containing active ingredients offered OTC for use as a smoking deterrent). Since there are no active OTC smoking deterrent ingredients generally recognized as safe and effective, **NICOTINE/OUT** is an unapproved new drug that may not be marketed without an approved New Drug Application. In addition, it is a new drug based on its being offered for sublingual administration.

Your product **SEA SALT NASAL SPRAY**: is labeled "A BUFFERED ISOTONIC NASAL SPRAY FOR ALLERGY RELIEF, NASAL DRYNESS, AND SINUS CONGESTION." Products for allergy relief and/or sinus congestions are subject to the final monograph for cold, cough, allergy, bronchodilator, and antiasthmatic drug products for OTC human use as published in 21 CFR 341. Your product **SEA SALT**

NASAL SPRAY does not meet the monograph and is, therefore, a new drug that may not be marketed without an approved New Drug Application.

DIATOMACEOUS EARTH: is labeled "TO CONTROL PARASITES AND WORMS IN THE DIGESTIVE SYSTEM;" **SUPER COLO$_2$ZONE** with **EDTA** is labeled "NOT just a laxative -- . . . kills parasites and worms; . . ." and your product **DYNAMQ$_2$** is labeled, "Provides continuous oxygen for effective cleansing of anaerobic bacteria, parasites and fungi." Products intended to kill internal parasites are anthelmintics and are subject to the final monograph for anthelmintics drug products for OTC human use as published in 21 CFR 357.101-180. These do not meet the monograph and are, therefore, new drugs that may not be marketed without an approved New Drug Application.

You also have several products offered for sublingual or buccal administration. Although the labels for these products direct the user to swallow, they first instruct the user to either hold the product under the tongue or in the mouth for 30 seconds to one minute before swallowing. Further, promotional labeling for these products, such as the "Product Information Booklet" (page 6) describes the virtues of sublingual administration and states most of your "liquid products are specially formulated for sublingual use, to result in maximum oral absorption." The description continues by stating that these products are formulated to buffer the digestive effect of saliva, making them 7 to 30 times more effective than products prepared for digestion, and "Sublingual application is more reliable than application by digestion . . . It's also significantly faster!"

The Food and Drug Administration does not consider sublingual products or products absorbed into the body through oral mucosa to be foods, since they are intended to bypass the alimentary canal by direct absorption through the sublingual or buccal mucosa. Products that are not intended for ingestion do not meet the definition of a "dietary supplement" as defined in section 201(ff)(2)(A)(I) of the Act. They are regarded as drugs within the meaning of section 201(g)(1) of the Act and new drugs within the meaning of section 201(p) of the Act. Accordingly, marketing of the following **Vitamin/Mineral Drug Products Offered for Sublingual or Buccal Administration** by your firm is in violation of the Act.

B12/Folic Acid Boost (Recommended by pain clinics worldwide)
Cell-regen (for healing)
Colloidal Gold (For inflammation, arthritis & other problems)
Colloidal Gold-
Colloidal silvers
Eden's promise (Libido Enhancer)
FM
G3 factors (circulatory system enhancer)
Ginkgo Biloba drops
Ginkgo biloba whole leaf extract
Nicotine/out (Nicotine detoxifier and "quitting aid")
Oxy-DHEA
Oxy-dioscorea
Oxy-dioscorea (precursor to DHE)
Oxy-herbs

Oxy-herbs (Some useful for pain and healing)
Oxy-melatonin
Oxy-moxy
Oxy-MSM with Vitamin C
O2C
O2B1
Pure deanol
Super oxy DMAE-PABA
Zinc, Manganese & B6 Boost

The products listed above are "new drugs" (section 201(p) of the Act) which may not be legally marketed in this country without an approved New Drug Application (section 505(a) of the Act)

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered (section 502(f)(1) of the Act) They are further misbranded because the labeling suggests that these products are safe and effective for their intended uses, when, in fact, this has not been established (section 502(a) of the Act).

The "Product Information Booklet" also contains therapeutic claims for a number of additional products and product kits These claims may also cause these products to be misbranded These products and claims include the following

COLO ZONE: "ridding the body of anaerobic invaders, parasites and fungus." easier stabilization of blood sugars".

B12/FOLIC ACID BOOST: "chronic pain," "chronic fatigue," ADHD, "sciatica and other neurological pain";

OXY-DISCOREA: obesity;

PURE DEANOL: included in your kits for chronic pain and ADHD;

ZINC, MANGANESE and B_6 BOOST: "prostate gland enlargement," "prevent benign[prostatic] hypertrophy";

OXY-MOXY: "aids metabolism and absorption of...medicines," "asthma and emphysema," "people undergoing radiation therapy," "Bronchitis, Pneumonia, Fibromyalgia." "equivalent of a tank of medical oxygen";

OXY-COOLER: "illness producing anaerobic bacteria, parasites (such as giardia) and fungi (such as Candida) that invade us and cause harm";

Innuit Omega Oils: [lower rate of] "arteriosclerosis and breast cancer," "substitute for aspirin in 'thinning the blood,'" "avoid or minimize hypertension, arthritis, migraines, infertility".

DLPA/DIET: "painkilling and depression-lifting",

Oxy-Herbs: "some useful for pain and healing"

Burdock Root	migraines
Eyebright	eye inflammations, colds, hay fever
Hawthorn	hypotensive, antispasmodic
Licorice Root	anti-inflammatory
Pau D'Arco	hypoglucaemiant
Sarsaparilla	diuretic, antifebrile, rheumatism, kidney trouble
Black Cohosh Root	antispasmodic,
Feverfew	migraine, arthritis, menstrual problems, tinnitus
Odorless Garlic	blood pressure normalizer, antimicrobial,
St John's Wort	antidepressant, bronchitis/asthma
Yellow Dock Wort	laxative,

O_2 K: "to rid the body of the 'hangers on [bacterial and parasites]' that survive the active cleansing." "high fever." "diarrhea";

O_2 B1: "fever," ADHD;

O_2C: "healing of wounds," "prevent high blood pressure and hardening of the arteries, and decreases the severity of colds"; and

G.I./Colon Six-Pack: "Gastrointestinal and colon problems" "Heartburn, Candida, Diverticulitis, Diarrhea, Gas, Ulcer, Malabsorption, Ileitis, Constipation, Colitis, Irritable Bowel Syndrome, Parasites and Worms inflammation," "for knocking out anaerobic invaders," "Win the war with the myriad of invaders who cause gastrointestinal distress and G.I. related illnesses."

Labeling for kits, such as, **BRAIN POWER NUTRITIONAL KIT, CHRONIC PAIN PACKAGE, FM NUTRITIONAL PACKAGE, and DIET KIT** include claims for individual products. These claims misbrand both the individual products, as well as the kits.

In addition to the violations previously mentioned in this Warning Letter pertaining to your human drug products, we have found similar violations with regards to your animal drug products.

Animal drugs are defined the same as human drugs, namely any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure or function of the body of man or other animals, is regarded as a "drug." Unless an animal drug is generally recognized by qualified experts as safe and effective for its labeled intended uses, it is a "new animal drug" under the law [Section 201(v) of the Act] A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA)

Our review of the labeling of your animal drug products reveals that they contain therapeutic claims, which causes them to be new animal drugs. These new animal drugs include, but are not limited to COLLOIDAL SILVER FOR PETS and COLLOIDAL GOLD FOR PETS Your COLLOIDAL SILVER FOR PETS

is labeled in part "TO FIGHT INFECTION and KEEP YOUR PET FREE OF PARASITES" and your **COLLOIDAL GOLD FOR PETS** is labeled in part "FIGHTS JOINT INFLAMMATION Ideal for older pets - or any pet who suffers from arthritis". We consider these drugs to be adulterated within the meaning of Section 501(a)(5) of the Act in that these are new animal drugs, which are unsafe within the meaning of Section 512 of the Act. Under this Section, a new animal drug is considered to be unsafe unless there is an approved NADA for the product. According to our records, you do not hold a NADA for any of your animal drug products.

We also consider your new animal drugs to be misbranded within the meaning of Section 502(f)(1) of the Act. This particular Section states that a drug is misbranded unless its labeling bears adequate directions for its intended use. The intended use of a drug can be established in many ways. For example, it can be established by advertisements in catalogs, newspapers, magazines, or by claims made on the Internet or by verbal statements made by product sales representatives.

You are using promotional material, such as your "Product Information Book," which contains therapeutic claims, which are unsubstantiated in the scientific literature. A drug product must have adequate directions for all its uses, as defined in 21 CFR 201.5, including those which do not appear on its labeling. Product labels with adequate directions for use cannot be written for drug products with unsubstantiated therapeutic claims.

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in an enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. Include an explanation of each step being taken to identify and make corrections and assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which you will implement the corrections.

For your information, we note that your firm's Internet web site contains similar or additional disease claims for your products, including additional claims for the MSM containing products such as depression, arthritis, gastrointestinal disorders and combating parasitic, microbial and fungal problems. Internet claims can serve to establish the intended use of a product and cause it to be a drug.

For your information, as stated in our Notice published in the Federal Register, Vol. 61, No. 78, on Monday, April 22, 1996, the Dietary Supplement Health and Education Act (know as DSHEA) of 1994 does not apply to animal products. A copy of this Notice is included for your review.

If you have any questions you may contact Barbara J. Rincon, Consumer Safety Officer at (949) 798-7731. Your reply should be addressed to:

Thomas L. Sawyer
Director Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Elaine C. Messa
District Director

cc: California Department of Health Services
Food & Drug Branch